

8. (Amended) A flexible plastic bag for recirculation washing of blood cells which has a top outlet port and a bottom inlet port and an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag and having a closed bottom end, wherein a less dense suspension of blood cells is withdrawn through said top outlet port for further processing, and a bubble trap at the top which comprises plastic tubing extending from the top outlet port into the bag inside the mesh tube.

REMARKS

Applicants submit this amendment in connection with the above-identified application in response to the Office Action mailed July 18, 2002. In this Amendment, claims 6-9 are currently pending. For the reasons set forth below, it is submitted that claims 6-9 are in condition for allowance and allowance of the application is respectfully requested.

Rejections under 35 USC §102 and 35 USC §103

In the Office Action, claim 6 was rejected under 35 U.S.C. §102(e) as being unpatentable over *Japuntich* (U.S. Pat. No. 5,695,489). For the reasons set forth below, Applicants respectfully traverse the rejection of claim 6 over the art and respectfully submit that the amended claim defines patentable subject matter over the prior art.

Amended claim 6 of the present invention recites a flexible plastic bag or reservoir for recirculation washing of blood cells which has a bottom inlet port and a top outlet port through which a less dense suspension of blood cells is withdrawn from the bag or reservoir for further processing. The flexible plastic bag or reservoir for recirculation washing of blood cells also includes an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag. Because the integral coarse filter is semi-rigid, it holds open a path through the otherwise collapsed bag or reservoir for the cells to move up to the top outlet port.

In contrast to the present invention, the *Japuntich* reference discloses a device for receiving, storing, filtering, and reinfusing a patient's blood. The device includes a container (12) having an inlet port (14) to receive blood from a patient and a first outlet

port (16) and a second outlet port (56) for reinfusing blood back into the patient (see Fig. 1). The *Japuntich* reference does not disclose or suggest a recirculation wash bag, nor does the *Japuntich* reference disclose or suggest preferentially withdrawing a less dense suspension of blood cells from a recirculation wash bag through a top port.

In the *Japuntich* reference, blood is withdrawn from the first outlet port (16) and second outlet port (56). The inlet port is connected to a transfer tube (26), and the distal end (28) of the transfer tube is connected to a collection cannister (not shown). A patient's blood is first drained or suctioned into the collection cannister and then transferred into the container (12) through the transfer tube via the inlet port. Collected blood from the container (12) is reinfused back into the patient by opening the outlet port (16). Thus, the *Japuntich* reference does not disclose or suggest reintroducing filtered blood back into either the collection cannister or the container (12) for further processing as recited in amended claim 6 of the present application.

Furthermore, the inlet port is located at an upper portion of the container (12), and the first and second outlet ports are located at a bottom portion of the container (12). In addition, the *Japuntich* reference discloses numerous embodiments of a separating means (32), which is used to keep the filtering material (30) from collapsing upon itself. (See col. 4, lines 3-6 and col. 4, lines 38-64). As such, the *Japuntich* reference does not disclose or suggest a bag having a top port for withdrawing blood cells and a bottom port for receiving blood cells, nor does it disclose a semi-rigid filter that holds open a path through the otherwise collapsed bag or reservoir for the cells to move up to the top outlet port, as recited in amended claim 6 of the present application.

In the Office Action, claim 7 was rejected under 35 U.S.C. §102(b) as being anticipated by *Hauer et al.* (U.S. Pat. No. 4,443,220). For the reasons set forth below, Applicants respectfully traverse the rejection of claim 7 over the art and respectfully submit that the amended claim defines patentable subject matter over the prior art.

Amended claim 7 of the present invention recites a flexible plastic bag or reservoir for recirculation washing of blood cells which has a top outlet port and a bottom inlet port. In addition, the flexible plastic bag or reservoir for recirculation

washing of blood cells also includes a bubble trap at the top, which comprises plastic tubing extending into the bag or reservoir from the top outlet port.

In contrast to the present invention, the *Hauer* reference discloses a device for the collection, temporary storage and transfer of whole blood to a patient. The device includes a collapsible collection bag (14) and a stent (16) that is assembled with the bag to hold it in distended form. The bottom of the bag has a pair of integrally molded tubes (25, 26) through which the contents of the bag may be transferred to a patient or to a receiving apparatus. Two additional intake tubes (32, 34) are located near the top, with tube (32) acting as an air vent in certain procedures. The *Hauer* reference does not disclose or suggest a recirculation wash bag, nor does the *Hauer* reference disclose or suggest a bubble trap extending into the bag or reservoir from the top outlet port.

In the *Hauer* reference, blood is withdrawn from the pair of integrally molded tubes (25, 26), which are located near the bottom of the bag, and blood is transferred into the bag via the fluid intake port (34) positioned near the top of the bag. Moreover, the air vent/bubble trap of the *Hauer* device comprises a tube/port (32) that extends into the bag and is separate from the fluid intake port (34). As such, the *Hauer* reference does not disclose or suggest a bag having a top port for withdrawing blood cells and a bottom port for receiving blood cells, nor does it disclose a bubble trap/air vent comprising a tube that extends into the bag via the top outlet port, as recited in amended claim 7 of the present application.

In the Office Action, claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over *Japuntich* in view of *Hauer et al.* For the reasons set forth below, Applicants respectfully traverse the rejection of claim 8 over the art and respectfully submit that the amended claim defines patentable subject matter over the prior art.

Amended claim 8 of the present invention recites a flexible plastic bag for recirculation washing of blood cells, which has a top outlet port and a bottom inlet port. The bag also includes an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag and having a closed bottom end, wherein a less dense suspension of blood cells is withdrawn through said top outlet port for further processing. In addition, the bag includes a

bubble trap at the top, which comprises plastic tubing extending from the top outlet port into the bag inside the mesh tube.

As discussed above, the cited references do not disclose or suggest a bag having a top port for withdrawing blood cells and a bottom port for receiving blood cells, nor do they disclose a semi-rigid filter that holds open a path through the otherwise collapsed bag or reservoir for the cells to move up through the top outlet port. These references are further deficient in that they do not disclose a bubble trap/air vent comprising a tube that extends into the bag via the top outlet port as recited in amended claim 8 of the present application.

Therefore, for at least these reasons, it is submitted that the *Japuntich* and *Hauer* references, either alone or in combination, neither anticipate nor render obvious the invention as recited in amended claims 6-8. Further, for at least these same reasons, it is submitted that claim 9, which depends from independent claim 8, is also allowable over the cited prior art. However, the claim dependent to claim 8 further distinguishes over the prior art and thus does not stand or fall with the allowability of claim 8.

CONCLUSION

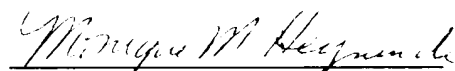
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

In view of the foregoing, it is submitted that all pending claims 6-9 are in condition for immediate allowance, and such action is respectfully requested. However, if for any reason direct communication with Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1901.

Respectfully submitted,

Dated: 1/17/2005



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Version With Markings to Show Changes Made

6. (Amended) A flexible plastic bag or reservoir for recirculation washing of blood cells which has a top outlet port and a bottom inlet port and an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag, wherein a less dense suspension of blood cells is withdrawn through said top outlet port for further processing.

7. (Amended) A flexible plastic bag or reservoir for recirculation washing of blood cells which has a top outlet port and a bottom inlet port and a bubble trap at the top which comprises plastic tubing extending into the bag from the top outlet port.

8. (Amended) A flexible plastic bag for recirculation washing of blood cells which has a top outlet port and a bottom inlet port and an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag and having a closed bottom end, wherein a less dense suspension of blood cells is withdrawn through said top outlet port for further processing, and a bubble trap at the top which comprises plastic tubing extending from the top outlet port into the bag inside the mesh tube.